

REMARKS

Claim rejections under 35 USC §112

5 The Examiner rejected claims 81-83, 85-87, 90, 94-96, 98-105, 108-
113, and 118-122 under 35 U.S.C. § 112, second paragraph, as being indefinite for
failing to particularly point out and distinctly claim the subject matter which
Applicant regards as the invention. The Examiner cited improper use of ranges,
Markush language, multiple “and/or” clauses and trademarked names in the above
cited claims as grounds for the rejection. The rejections under 35 USC §112 have
10 been addressed by amendment of the claims.

 Claims reciting ‘preferably’ have been amended by deleting the
preferred embodiments. Applicant has introduced new dependent claims 124, 125
and 128, which are directed to more limiting embodiments originating from claims
15 81, 82 and 103, respectively.

 The term, ‘substantially’ has been deleted from the claims to which the
Examiner objected. Markush language has been amended according to the
Examiner’s suggestions.

20 Claims containing multiple ‘and/or’ clauses have been amended.
Original claim 95 has been split up into amended claim 95 and new claims 126 and
127 to cover all alternatives. Original claim 113 was split similarly (amended claim
113 and new claims 129 and 130).

To create correct antecedent basis, the following further amendments have been made:

Claim 90 has been split up into 90 (currently amended) and claim 131 (new);

5 Claim 104 has been split up into 104 (currently amended) and claim 132 (new);

Claim 105 has been split up into 105 (currently amended) and claim 133 (new);

10 Claim 106 has been split up into 106 (currently amended) and claim 134 (new);

Claim 122 has been split up into 122 (currently amended) and claim 135 (new); and

Claim 123 has been split up into 123 (currently amended) and claim 136 (new).

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Furthermore, the amended claims no longer contain references to trademarks. Applicant respectfully requests that in light of the amended claims the rejections under 35 U.S.C § 112 be withdrawn.

Claim rejections under 35 USC §103

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The Examiner has rejected a number of claims under 35 USC §103(a) in view of the disclosures of Graupner et al. (WO 98/04119) and Packard et al.(1993). The Examiner states that Graupner et al. disclose methods and systems

to provide for testing of individual volumes of milk, at various times, before or after the individual animal is identified, directs milk to one or more outlets or storage means, and stores the assessment data in an appropriate manner. Grauptner et al. do not teach the assessment of particles within a sample of milk wherein the particles
5 are somatic cells, blood particles or particles of body tissue. Grauptner et al. also do not teach the further assessment of temperature and/or pH or assessment of fat, protein or lactose concentration.

The Examiner further states that Packard et al. (J. AOAC Intl., 76:2,
10 297-305 (1993)) disclose automated sampling and assessment of several milk properties including somatic cell count, fat content, protein content, lactose content, and other solids in samples taken automatically. According to the Examiner, Packard et al. note the assessments were done by well known, often performed methods which appears to be the same methods as those encompassed by the claims.

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The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added a means for particle assessment to the method and system of Grauptner et al. One would have been motivated to add this step and a means for this step to have better assessed the
20 quality of milk being pumped. Applicant respectfully traverses this rejection.

Grauptner et al. discloses a device for automatic sorting of milk. The device directs milk to one of several outlets depending on a measured parameter

value. As the Examiner admits, the disclosure of Grauptner et al. does not include particle assessment nor does it suggest this possibility.

Applicant respectfully submits that the Examiner has misread the
5 Packard et al. (1993) reference. Packard et al. disclose only a method for the
automatic sampling of milk from bulk tanks after completion of the milking process.
According to the reference, subsequent to the sampling, the sample is analyzed in the
laboratory for a number of parameters, which may include an assessment of somatic
cells. The Packard reference is therefore, merely a study to determine whether using
10 an autosampling device to collect milk from a bulk storage container was as good as
or better than manually taking samples. The Packard reference does not disclose
automated testing of milk samples during milking, nor does it teach or suggest how
standard laboratory bench methods of testing various milk parameters would be
adapted for an automated milking system.

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To establish a *prima facie* case of obviousness, three basic criteria must
be met. First, there must be some suggestion or motivation, either in the references
themselves or in the knowledge generally available to one of ordinary skill in the art,
to modify the reference or to combine reference teachings. Second, there must be a
20 reasonable expectation of success. Finally, the prior art reference (or references
when combined) must teach or suggest all the claim limitations. Moreover, the
teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The burden is on the examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references. In re Deuel, 51
5 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). Only after that burden is met must the applicant come forward with arguments or evidence in rebuttal. Id. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants submit that the Examiner has failed to establish a
10 *prima facie* case of obviousness because the combination of Graupner et al. in view of Packard et al. does not teach each and every element of the claimed invention.

Packard et al. only disclose a method for automatically taking milk samples and then performing a laboratory analysis of samples taken after completion
15 of the milking process. Packard does not, when combined with the disclosure of Graupner et al., teach each and every element of the claimed invention, which concerns sorting of milk on the basis of a particle assessment during the milking process. Thus, combination of these two references does not provide the basis for a *prima facie* obviousness rejection.

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In fact, one of the novel and non-obvious aspects of the present invention is that, for the first time, regulation of a milking process based on an assessment of particles during milking has technically been made possible.

The present application is directed to a method (and a system) for regulating a milking process, i.e. a method that allows immediate regulation of the process based on the outcome of the assessment of the particles in the milk. While
5 Grauptner et al. describe a method that can perform immediate regulation of milking processes based on other types of assessments, neither it, nor the prior art, describes methods or means for particle assessment that are suitable for integration into the system of Grauptner et al.

10 In particular, a number of requirements need to be fulfilled to allow integration of a means for particle assessment into a system for the assessment of particles:

- 1) *accuracy* - is important for determining the quality of the milk;
- 2) *speed* - is important to allow real-time regulation of the milking process;
- 15 3) *robustness* - is important because the method is applied in a farm; and
- 4) *cost-effectiveness* - is important for the method to be of real commercial value.

Further in this regard, Applicant respectfully points out that the Packard reference does not describe how somatic cells are counted. The reference merely
20 refers to another document describing such an assay (Richardson, 1985). While Applicant has not yet been able to obtain a copy of this other document, other references to it suggest that it concerns a standard prior art method and system for carrying out automated fluorescent dye procedures.

Automated fluorescent dye procedures described in the prior art are generally only automated to the extent that a sample is taken automatically from a row of samples and analyzed automatically. The usual procedure is that, firstly, milk
5 samples are taken during the milking process at the farm. Then, the samples are transported to a central analysis laboratory where they are put into the queue of an automated counting instrument. The instrument automatically takes a sample and analyzes it. The results are then registered in a computer, and subsequently communicated back to the farm to be used in deciding whether the milk can be sold
10 and at what price. Thus, although the analysis is done automatically, the analysis instrument is not incorporated into the milking system, and the results are not used in the milking process in the sense that they are used to further regulate the milking process (step vii) of claim 80: *regulating the milking process based on any one or both of c) the at least one result obtained in iii), and d) the correlation obtained in*
15 *v)).*

Importantly, the instruments used in the prior art for counting somatic cells are not suitable for incorporation into a system for regulating a milking process. These instruments often use the principle of flow-cytometry, wherein an aliquot is
20 inserted into a stream of carrier fluid that separates the cells and passes them at high speed past a laser beam and detector means. Since the particles pass a detector at high speed, the detection time is short. Thus, very sensitive equipment is required to be able to detect particles.

Such sensitive equipment is far too elaborate and fragile to allow it to be installed in a farm setting. A milking stable environment is characterized by changing temperatures, changing humidity, dirt, vermin, risk for physical damage, etc. This is clearly not a suitable setting for placing sensitive laboratory equipment.

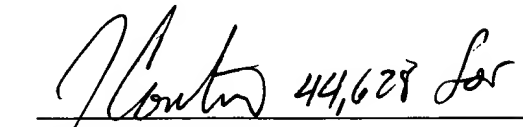
5 Moreover, these instruments require a trained operator and regular calibration, as instrumental drift is a known problem of flow cytometers. Therefore, in spite of having been available for many years, flow cytometry is currently only carried out in laboratory settings.

10 In conclusion, while the number of somatic cells has long been known to be one of the best parameters for determination of mastitis, Applicant has succeeded in developing a method that allows regulation of a milking process based on an assessment of this parameter. Nothing in the prior art teaches or suggests the technical solution provided by the inventor.

15 All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding
20 Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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Date: March 16, 2004

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Atty. Docket: 12596/P666116US0
HBJ/JGC/clc